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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,613	06/27/2001	Shawn Shui-on Leung	655	4914

7590

09/13/2004

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/892,613	LEUNG, SHAWN SHUI-ON	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15 and 20-39 is/are pending in the application.
- 4a) Of the above claim(s) 14, 15 and 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-30 is/are rejected.
- 7) ☒ Claim(s) 31-39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 25-39 have been added, claims 1-13 have been canceled.
2. Claims 14-15, 20-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in Paper No. 14.
3. Claims 25-39 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
5. The following Office Action contains NEW GROUNDS of rejection.

Claim Objections

6. Claims 31-39 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on a multiple dependent claim. Claims 31-39 are dependent on claims 27, 28, 29, or 30 which recite claims 25 or 26. See MPEP § 608.01(n). Accordingly, the claims 31-39 have not been further treated on the merits.

Rejections Withdrawn

7. The rejection of claims 1-13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention is withdrawn in view of the amendments to the claims.

8. The rejection of claims 1-13 under 35 U.S.C. 102(b) as being anticipated by Queen et al (U.S. Patent 5,693,762, issued 12/97, IDS #1 ½) is withdrawn in view of the amendments to the claims.

9. The rejection of claims 1-13 under 35 U.S.C. 112, first paragraph, for enablement is withdrawn in view of the amendments to the claims

Response to Arguments

10. The rejection of newly added claims 25-30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response filed 6/28/04 has been carefully considered but is deemed not to be persuasive. The response states that "within ten-fold" can be found on page 2, line 10 of the specification (see page 14 of response). In response to this argument, at the recited page and line the text states "replacement of framework sequences without further modifications can result in the loss of affinity for the antigens, sometimes as much as 10-fold or more". This does not support a re-engineered antibody that binds antigen within 10-fold of the parent antibody. The cited line is not in the context of re-engineering to obtain an affinity of 10 fold to the parent. The text only states that without further modifications affinity can be lost as much as 10 fold or more.

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11. The rejection of newly added claims 25, 27-30 under 35 U.S.C. 102(b) as being anticipated by Ohtomo et al (Molecular Immunology 32:407-416, 1995) is maintained.

The response filed 6/28/04 has been carefully considered but is deemed not to be persuasive. The response states that Exhibit A is diagrams illustrating the difference between Framework-patching and humanization and Ohtomo et al does not anticipate the invention because the method of framework-patching is different from humanization and the difference is in immunogenicity and Ohtomo's antibodies are not structurally identical to the claimed antibodies (see pages 18-20). In response to this argument, the method of how the antibodies are made is immaterial if the structures are the same. In response to the argument that the structures are not the same, the claims recite one FR from one immunoglobulin and others from another immunoglobulin for which Ohtomo et al's antibody is. It is unclear how the structures are different.

The antibodies of Ohtomo read on the claims.

12. The rejection of claims 25-30 under 35 U.S.C. 103(a) as being unpatentable over Ohtomo et al (Molecular Immunology 32:407-416, 1995) and further in view of Queen et al (US Patent 5,693,762, issued 12/97, IDS #11/2) is maintained.

The response filed 6/28/04 has been carefully considered but is deemed not to be persuasive. The response reiterates the arguments of Ohtomo et al above and then argues residues re-introduced are different in framework-patching than in Queen et al (see page 22-24). In response to this argument, the claims requiring re-introducing residues are not being examined due to improper multiple dependency, however, if they

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were considered, the claims only require replacement of residues adjacent or within a certain distance to a CDR there is nothing in the claims requiring the re-introduced residues not being murine.

The response then states that FR1, FR2, and FR3 should be intact in the Queen reference and Ohtomo does not teach altering the FR1, FR2, or FR3 (see page 25-27). In response to this argument, Ohtomo et al clearly teaches looking for the most homologous FR from the human database or consensus sequence. Ohtomo et al teach comparison of the Fr wherein each is compared. Therefore, it would be obvious to have a FR1 from one immunoglobulin and FR2 from another if the most homology was found in a different immunoglobulin (wherein FR1 was most homologous to one human immunoglobulin and FR2 was most homologous to another immunoglobulin). This is because Ohtomo et al chose FR4 to be different based on homology to another immunoglobulin. Therefore, the method of Ohtomo would use comparisons of each FR.

The response further argues methods of the invention vs. Queen and Ohtomo and which residues to back mutate (see pages 29-31). In response to this argument, the claims are to products not methods and as stated above the products are the same as claimed and in the prior art and the claims only require replacement of residues adjacent or within a certain distance to a CDR there is nothing in the claims requiring the re-introduced residues not being murine.

The response then states that the homology of Ohtomo and Queen is in the context of the whole FR sequence and not individualized Fr and this is unprecedented (and assumed to be the invention) (see page 31). In response to this argument,

Ohtomo et al teach comparison of the Fr wherein each is compared. Therefore, it would be obvious to have a FR1 from one immunoglobulin and FR2 from another if the most homology was found in a different immunoglobulin (wherein FR1 was most homologous to one human immunoglobulin and FR2 was most homologous to another immunoglobulin). This is because Ohtomo et al chose FR4 to be different based on homology to another immunoglobulin. Therefore, the method of Ohtomo would use comparisons of each FR.

The following are NEW GROUNDS of rejections

Claim Rejections - 35 USC § 112

13. Claims 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 25 and 26 and those dependent from these claims are indefinite for reciting "whereas not all the replaced FR1...of the re-engineered immunoglobulin light chain...." Because it is not clear if this is included in the proviso or not. In addition, it is unclear if you have a heavy chain that has the proviso recited if the light chain must also have the recited limitation above.

b. Claims 25-30 are indefinite for reciting "derived" in claims 25 and 26 because it is unclear how the sequences are derived. Does the term mean the FR sequences

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can be altered or does the term mean the FR are the same identical sequences but are "from" different sources?

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571)

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272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached on (571) 272-0787.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER